

Appl. No. 10/717,746
Amdt. dated August 21, 2006
Reply to Office Action of June 20, 2006

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Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (withdrawn): A composition comprising a crude extract containing at least one annonaceous acetogenin, wherein the crude extract is prepared from at least one species in the group consisting of the annonaceous genera *Asimina*, *Annona*, *Goniothalamus*, *Uvaria*, *Disepalum*, *Xylopia*, and *Rollinia*.

Claim 2 (withdrawn): A composition in accordance with claim 1, wherein the crude extract is in a capsule form.

Claim 3 (withdrawn): A composition in accordance with claim 1, wherein the crude extract is in tablet form.

Claim 4 (withdrawn): A composition in accordance with claim 1, wherein the crude extract is in tincture or liquid form.

Claim 5 (withdrawn): A composition in accordance with claim 1, wherein said species is *Asimina triloba*.

Claim 6 (withdrawn): A composition in accordance with claim 5, wherein the crude extract is prepared from twigs of the *Asimina triloba*.

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Claim 7 (original): A method for extracting a crude extract, comprising the steps of:

(a) obtaining one or more twig, unripe fruit, seed, bark or other bioactive plant part, or any combination thereof, the one or more twig, unripe fruit, seed, bark or other bioactive plant part being of a genus selected from the group consisting of Asimina, Annona, Goniolanthus, Uvaria, Disepalum, Xylopia, and Rollinia;

(b) drying the one or more twig, unripe fruit, seed, bark or other bioactive plant part in a forced air drier at less than 50° C to form a mass;

(c) placing the mass in a sieve to form a sieved product;

(d) pulverizing the sieved product in a chipper to form a pulverized product;

(e) placing the pulverized product in a percolator;

(f) performing at least one water extraction on the pulverized product;

(g) performing at least one ethanol extraction on the pulverized product to provide an ethanolic extract;

(h) concentrating the ethanolic extract, in vacuo, at about 50° C, to form a syrup;

(i) allowing the syrup to settle into a crude extract layer and a water layer;

(j) removing the water layer from the crude extract layer to form a concentrate; and

(k) spray drying the concentrate onto an inert carrier to facilitate encapsulation or tableting.

Claim 8 (original): The method of claim 7, further comprising the step of standardizing the crude extract for zero percent moisture and an LC₅₀ of 0.5 ppm in a BST.

Claim 9 (original): The method of claim 7, further comprising the step of standardizing the crude extract for a range on 10-40% moisture, and an LC₅₀ value in a range of 0.2-0.8 ppm in a BST.

Claim 10 (withdrawn): A method for decreasing tumor antigen levels by administering an effective amount of the composition of claim 1.

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Claim 11 (withdrawn): A method for decreasing tumor size by administering an effective amount of the composition of claim 1.

Claim 12 (withdrawn): A method for treatment of cancer by administering 12.5 mg four times daily of the composition of claim 1.

Claim 13 (withdrawn): A method for determining a patient's tolerance to a crude extract including the steps of:

(a) ingesting 12.5 mg of a composition comprising a crude extract containing at least one annonaceous acetogenin, wherein said crude extract is prepared from at least one species from the group consisting of the annonaceous genera *Asimina*, *Annona*, *Goniothalamus*, *Uvaria*, *Disepalum*, *Xylopia*, or *Rollinia*, on day one;

(b) ingesting 25 mg of the crude extract composition on day two;

(c) ingesting 37.5 mg of the crude extract composition on day three; and

(d) ingesting 50 mg of the crude extract on day four.

Claim 14 (withdrawn): The method of claim 13, further comprising the steps of:

(a) evaluating the patient's tolerance daily after ingesting the crude extract.

Claim 15 (new): A method for extracting a crude extract, comprising:

(a) obtaining one or more twig, unripe fruit, seed, bark or other bioactive plant part, or any combination thereof, the one or more twig, unripe fruit, seed, bark or other bioactive plant part being of a genus chosen from: *Asimina*, *Annona*, *Goniothalamus*, *Uvaria*, *Disepalum*, *Xylopia*, and *Rollinia*;

(b) drying the one or more twig, unripe fruit, seed, bark or other bioactive plant part to form a mass;

(c) performing at least one water extraction on the mass;

(d) performing at least one alcohol extraction on the mass to provide an alcohol extract;

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- (e) concentrating the alcohol extract; and
- (f) removing water from the alcohol extract to form a crude extract.

Claim 16 (new): The method of claim 15, further comprising:

- (a) pulverizing the one or more twig, unripe fruit, seed, bark or other bioactive plant part before performing the at least one water and at least one alcohol extraction.

Claim 17 (new): The method of claim 15, further comprising:

- (a) allowing the concentrated alcohol extract to settle into a crude extract layer and a water layer before removing water from the alcohol extract.

Claim 18 (new): The method of claim 15, further comprising:

- (a) spray drying the crude extract onto an inert carrier to facilitate encapsulation or tableting.

Claim 19 (new): The method of claim 15, wherein the alcohol extraction is an ethanol extraction.

Claim 20 (new): The method of claim 15, further comprising:

- (a) standardizing the crude extract for a range on 10-40% moisture, and an LC₅₀ value in a range of 0.2-0.8 ppm in a BST.